UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

May 9, 2016

MEMORANDUM

Subject: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution 1, EPA Reg. No. 63761-8; DP Barcode: D431263.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Julie Chao RM33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Sterilex Corporation
111 Lake Front Drive
Hunt Valley, MD 21030

Formulation from the Label:

Active Ingredient	% by wt.
n-Akyl (68% C_{12}, 32% C_{14}) dimethylethylbenzyl ammonium Chloride	3.00 %
n-Akyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethylbenzyl ammonium Chloride	3.00 %
Hydrogen peroxide	6.30 %
Other Ingredients	87.70 %
Total	100.00 %

I. BACKGROUND

The product, Sterilex Ultra Disinfectant Cleaner Solution 1 (EPA Reg. No. 63761-8), is an EPA-registered component of a two-part product. The product must be used with Sterilex Ultra Activator Solution. The mixture is approved cleaner and disinfectant with bactericidal and virucidal activities, for use on hard, non-porous surfaces in institutional, household, commercial, and hospital or medical environments. The applicant requested an amendment to the registration of this product to add claims for additional organisms and add/revise various marketing claims. Study was conducted at Antimicrobial Test Laboratories, located at 1304 W. Industrial Blvd, Round Rock, TX 78681, and at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D431263 contained a letter from the applicant to EPA (dated January 8, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), eight (8) studies (MRID Nos. 498091-01 through 498091-08), Statements of No Data Confidentiality Claims for each study, and the proposed label (revision 637618-12212015). Note that, according to the Registrant, the additional activators included on the proposed label represent a change in brand name only.

II. USE DIRECTIONS

GENERAL ONE STEP DISINFECTION AND CLEANING DIRECTIONS FOR HARD. NON-POROUS SURFACES

[Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP)[Ultra Coi-Al San], when mixed with [Sterilex Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Coi-Al Activator] [Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus], is a one-step, cleaner and hospital-use disinfectant at 12.8 - 16.0 fl. oz. of [Sterilex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Coi-Al San] and 12.8 - 16.0 fl. oz. of [Sterilex Ultra Activator Solution] [or][Ultra Activator SM] [Ultra Coi-Al Activator][Ultra Soft Metal Activator][Ultra Aluminum Safe Activator] [Ultra Activator Plus] per gallon of water (1:1 10 - 1:1:8), Bactericidal according to the current AOAC UseDilution

Test Method modified in the presence of 400 ppm hard water plus 5% organic serum against:

[Pseudomonas aeruginosa (Pseudomonas) [ATCC # 15442]]
[Staphylococcus aureus (Staph) {ATCC# 6538]]
[Staphylococcus aureus - Methicillin Resistant {ATCC # 33591) {MRSA]]
[Salmonella enterica (Salmonella) [ATCC # 10708])
[Salmonella enterica enterica enteritidis {ATCC 13076]]
[Salmonella enterica enterica heidelberg {ATCC 8326]]
[Escherichia coli O157:H7 [ATCC # 35150]]
[Listeria monocytogenes [ATCC # 19111]]
[Campylobacter jejuni [ATCC 29428]]

APPLICATION INSTRUCTIONS:

To clean and disinfect in one step, remove gross filth [soil} from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 12.8 - 16.0 ounces [378.5 -473.2 ml] of [Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP][Ultra Coi-Al San] and 12.8 - 16.0 ounces [378.5 - 473.2 ml) of Sterilex [Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Coi-Al Activator] [Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus] to 1 gal. [3.78 L] of water. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse.

Use product within 8 hours of mixing [Sterilex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Coi·Al San] and Sterilex Ultra Activator Solution] [or][Ultra Activator SM][Ultra Coi-Al Activator][Ultra Soft Metal Activator][Ultra Aluminum Safe Activator] [Ultra Activator Plus].

SPOILAGE ORGANISMS
(Sterilex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Coi-Al San] , when mixed with [Sterilex Ultra Activator Solution} [or][Ultra Activator SM)[Ultra Coi-Al Activator][Ultra Soft Metal Activator][Ultra Aluminum Safe Activator] [Ultra Activator Plus]kills the spoilage organisms, [Trichophyton mentagrophytes [(ATCC 9533)]], on hard, inanimate surfaces in one step at [12.8 - 16.0 oz. of [Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP] [Ultra Coi-Al San] and 12.8 - 16.0 oz. of [Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Col-Al Activator] [Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus] per gallon of water], according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum.

VIRUSES
Avian Influenza:
[Sterilex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Coi-Al San], when mixed with [Sterilex Ultra Activator Solution] [or][Ultra Activator SM][Ultra Coi-Al Activator][Ultra Soft Metal Activator][Ultra Aluminum Safe Activator) [Ultra Activator Plus], is effective against Avian Influenza A on hard, inanimate surfaces in one step at 2 - 4 fl. oz. of [Sterilex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Coj.Al San] and 2 -4 fl. oz. ofSterilex Ultra Activator Solution] [or] [Ultra Activator SM][Ultra Coi-Al Activator][Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus] per gallon of water (1:1:64), with a 5 minute contact time in the presence of 400 ppm hard water and organic soil. Remove gross filth [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 2 - 4 fl. oz. of [Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP][Ultra Coi-Al San] and 2 -4 fl. oz. of [Sterilex Ultra Activator Solution] [or][Ultra Activator SM][Ultra Coi-Al Activator][Ultra Soft Metal Activator][Ultra Aluminum Safe Activator] [Ultra Activator Plus) to 1 gal. [3.78 L] of water. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain wet for at least 5 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use product within 8 hours of mixing [Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP] [Ultra Coi-Al San] and [Sterilex Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Coi-Al Activator}[Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus].

[Feline Calicivirus] [Norovirus] [Rotavirus]:
[Sterilex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Col·Al San], when mixed with [Sterilex Ultra Activator Solution] [or)[Ultra Activator SM][Ultra Coi-Al Activator][Ultra Soft Metal Activator][Ultra Aluminum Safe Activator][Ultra Activator Plus], Is effective against viruses on hard, inanimate surfaces in one step at [12.8-16.0 oz. of [Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP] [Ultra Coi·Al San] and 12.8-16.0 oz. of [Sterilex Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Col-Al Activator][Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus] per gallon of water], with a 10 minute contact time in the presence of 400 ppm hard water and organic soil.

PED Virus:
[Sterilex Ultra Disinfectant Cleaner Solution 1] [Ultra CIP] [Ultra Col-Al San], when mixed with [Sterllex Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Coi-Al Activator] [Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus], is effective against Porcine Epidemic Diarrhea Virus (PEDv) on hard, inanimate surfaces at 12.8 - 16.0 fl. oz. of [SterUex Ultra Disinfectant Cleaner Solution 1][Ultra CIP][Ultra Coi-Al San] and 12.8 - 16.0 fl. oz. of [Sterilex Ultra Activator Solution] [or] [Ultra Activator SM] [Ultra Col-Al Activator] [Ultra Soft Metal Activator] [Ultra Aluminum Safe Activator] [Ultra Activator Plus] per gallon of water, with a 10 minute contact time in the presence of 400 ppm hard water.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use- Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots at LCL. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray or towelette products) may be modified to conform to appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots at LCL must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides - Use of a Surrogate Virus: For certain viruses, there are no *in vitro* systems or *in vivo* animal models (except for humans and chimpanzees). The Agency permits the testing of surrogate viruses in these cases, for example, Bovine Viral Diarrhea virus as a surrogate for human Hepatitis C virus, Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus, and Feline Calicivirus as a surrogate for Norwalk virus.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5% serum.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 498091-01 "GLP AOAC Use-Dilution Method, for Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution; Test Organisms: *Salmonella enterica* (ATCC 13076)", by Nicholas Garcia. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 06, 2015. Project Number GLP1269.

This study was conducted against *Salmonella enterica* (ATCC 13076). Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1307 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 10 parts of 400 ppm AOAC Synthetic Hard Water. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per lot were immersed 15±2 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The carriers were dried for 40±2 minutes at 35.5 – 35.6°C. Each carrier was exposed to 10 ml of the use solution for 9 minutes at 20.0°C. After exposure, the carriers were transferred to 10 ml of Modified Letheen Broth containing 0.1% Catalase to neutralize. All subcultures were incubated for 46 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

2. MRID 498091-02 "GLP AOAC Use-Dilution Method, for Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution; Test Organisms: *Salmonella enterica* (ATCC 8326)", by Nicholas Garcia. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 06, 2015. Project Number GLP1271.

This study was conducted against *Salmonella enterica* (ATCC 8326). Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1311 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 10 parts of 400 ppm AOAC Synthetic Hard Water. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per lot were immersed 15±2 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The carriers were dried for 38 minutes at 35.6 – 35.7°C. Each carrier was exposed to 10 ml of the use solution for 9 minutes at 20.0°C. After exposure, the carriers were transferred to 10 ml of Modified Letheen Broth containing 0.1% Catalase to neutralize. All subcultures were incubated for 46 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

3. MRID 498091-03 "GLP AOAC Use-Dilution Method, for Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution; Test Organisms: *Trichophyton mentagrophytes* (ATCC 9533)", by Nicholas Garcia. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 07, 2015. Project Number GLP1272.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1312 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 10 parts of 400ppm AOAC Synthetic Hard Water. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per lot were immersed 17 minutes in spore preparation, at a ratio of 1 carrier per 1.0 ml broth. The carriers were dried for 39 minutes at 35.5°C. Each carrier was exposed to 10 ml of the use solution for 9 minutes at 20±1°C. After exposure, the carriers were transferred to 10 ml of Modified Letheen Broth containing 0.1% Catalase to neutralize. All subcultures plates were incubated for 68±1 hours at 28.7-28.8°C. All neutralized subcultures were incubated for 10 days at 28.7-28.8°C. . Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 498091-04 "GLP AOAC Use-Dilution Method, for Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution; Test Organisms: *Campylobacter jejuni* (ATCC 29428)", by Nicholas Garcia. Study conducted at Antimicrobial Test Laboratories. Study completion date – August 12, 2015. Project Number GLP1302.

This study was conducted against *Campylobacter jejuni* (ATCC 29428). Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1309 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 10 parts of 400±10 ppm AOAC Synthetic Hard Water. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per lot were immersed 16 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The carriers were dried for 30 minutes at 25.6 – 25.7°C. Each carrier was exposed to 10 ml of the use solution for 9 minutes at 20±1°C. After exposure, the carriers were transferred to 10 ml of Fluid Thioglycollate Medium with 0.1% Catalase to neutralize. All subcultures were incubated for 4 days at 35.7-38.9°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation reported in the study was reviewed.

5. MRID 498091-05 "GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces, Test Organisms: Feline Calicivirus. Strain F-9 (ATCC VR-782)", by Erika Guin. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 14, 2015. Project Number GLP1274.

This study was conducted against Feline Calicivirus, Strain F-9 (ATCC VR-782), using Crandell Rees Feline Kidney (CRFK) cells (ATCC CCL-94) as the host system. Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1292 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 10 parts of 400±10 ppm AOAC Synthetic Hard Water. The stock virus culture was adjusted to contain a 5% organic soil load (Bovine Serum Albumen, Bovine Mucin, and Yeast Extract). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 25.6-26.7°C for 7 minutes at 57-58% relative humidity. For each lot of product, two (2) dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 9 minutes at 26.4-27.6°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephacryl (S-1000 SF) Gel Filtration Column, and diluted serially in Eagle's Minimum Essential Medium (EMEM) supplemented with 2% fetal bovine serum plus antibiotics [100 µg/ml Kanamycin Sulfate solution and Antibiotic-Antimycotic solution (100 units/ml Penicillin G, 100 µg/ml Streptomycin, and 0.25 µg/ml Amphotericin B)]. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 37±2°C in a humidified atmosphere of 5±1% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.55 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥3.75 $\log_{10}$** for both sets of batches.

Note: Protocol deviation reported in the study was reviewed.

6. MRID 498091-06 "GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces, Test Organisms: Influenza A (H3N2), Strain A/Victoria/361/2011 (ATCC/IRR FR-1061)", by Erika Guin. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 9, 2015. Project Number GLP1287.

This study was conducted against Influenza A (H3N2), Strain A/Victoria/361/2011 (ATCC/IRR FR-1061), using Madin-Dorby Canine Kidney (MDCK-ATL) cells (ATCC FR-926) as the host system. Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1322 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 64 parts of 400±10 ppm AOAC Synthetic Hard Water. The stock virus culture was adjusted to contain a 5% organic soil load (Bovine Serum Albumen, Bovine Mucin, and Yeast Extract). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 49 minutes at 4.9-5.3°C and 46-53% relative humidity. For each lot of product, one (1) dried virus film was individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 4.5 minutes at 26.6-26.7°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephacryl (S-1000 SF) Gel Filtration Column, and diluted serially in Dulbecco's Minimum Essential Medium (DMEM) supplemented with 0.18% Bovine Serum Albumen (Fraction V), 4 µg/ml Trypsin and antibiotics [100 µg/ml Kanamycin Sulfate solution and Antibiotic-Antimycotic solution (100 units/ml Penicillin G, 100 µg/ml Streptomycin, and 0.25 µg/ml Amphotericin B)]. MDCK-ATL cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 34±2°C in a humidified atmosphere of 5±1% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.8 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥4.0 $\log_{10}$** for both sets of batches.

7. MRID 498091-07 "GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces, Test Organisms: Human Rotavirus (Group A), Strain Wa (TC-Adapted) (ATCC VR-2018)", by Erika Guin. Study conducted at Antimicrobial Test Laboratories. Study completion date – August 21, 2015. Project Number GLP1314.

This study was conducted against Human Rotavirus (Group A), Strain Wa (TC-Adapted) (ATCC VR-2018), using Embryonic African Green Monkey Kidney (MA-104 Clone 1) Cells (ATCC CCL-2738.1) as the host system. Two lots sets (AM1-24A/AM1-129A and AM1-25B/AM1-129B) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATL protocol P1361 (copy provided). The product was prepared by mixing 1 part of Solution 1 and 1 part of Sterilex Ultra Activator Solution and 10 parts of 400±10 ppm AOAC Synthetic Hard Water. The stock virus culture was adjusted to contain a 5% organic soil load (Bovine Serum Albumen, Bovine Mucin, and Yeast Extract). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 64 minutes at 1.2-24.8°C and 39-45% relative humidity. For each lot of product, one (1) dried virus film was individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 9 minutes at 25.1-25.8°C and 45% relative humidity. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephacryl (S-1000 SF) Gel Filtration Column, and diluted serially in Eagle's Minimum Essential Medium (EMEM) supplemented with 4 µg/ml Trypsin and antibiotics [100 µg/ml Kanamycin Sulfate solution and Antibiotic-Antimycotic solution (100 units/ml Penicillin G, 100 µg/ml Streptomycin, and 0.25 µg/ml Amphotericin B)]. MA-104 Clone 1 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 37±2°C in a humidified atmosphere of 5±1% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.10 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥3.0 $\log_{10}$** for both sets of batches.

8. MRID 498091-08 "Virucidal Efficacy of a Disinfectant for Use on inanimate Environmental Surfaces" for Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces. Test Organisms: Porcine Epidemic Diarrhea Virus, Strain Colorado 2013 Isolate, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – October 27, 2014. Project Number A17336.

This study was conducted against Porcine Epidemic Diarrhea Virus, Strain Colorado 2013 Isolate, using Vero 76 cells (ATCC CRL-1587) as the host system. Two lots sets (2CB064A/BT32218 and 2CB064B/BT30898) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution, were tested according ATS Labs protocol SLX01082714.PEDV.2 (copy provided). The product was prepared by mixing 12.8 fl. oz. part of Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution and 1 gallon of 400 ppm AOAC Synthetic Hard Water. The stock virus culture was not adjusted to contain a 5% organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C and 30% relative humidity. For each lot of product, one (1) dried virus film was individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 minutes at 20.0°C and 45% relative humidity. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex LH-20 gel, and diluted serially in Minimum Essential Medium (MEM) supplemented with 2 µg/mL TPCK-trypsin, 10% (v/v) tryptose phosphate broth, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B. Vero 76 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.50 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥3.0 $\log_{10}$** for both sets of batches.

V. RESULTS

MRID Number	Organism	Contact Time	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count ($\log_{10}$ or CFU/ carrier)
			Lots AM1-24A/AM1-129A	Lots AM1-25B/AM1-129B	
498091-01	*Salmonella enterica* (ATCC 13076)	9 minutes	0/10	0/10	6.2
498091-02	*Salmonella enterica* (ATCC 8326)	9 minutes	0/10	0/10	6.08
498091-03	*Trichophyton mentagrophytes* (ATCC 9533)	9 minutes	0/10	0/10	4.78
498091-04	*Campylobacter jejuni* (ATCC 29428)	9 minutes	0/10	0/10	5.65

MRID Number Contact time	Organism	Description	Lots AM1-24A/AM1-129A	Lots AM1-25B/AM1-129B	Dried Virus Control (log_{10})
498091-05 **9 minutes**	Feline Calicivirus, Strain F-9 (ATCC VR-782)	10^{-2} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	5.25
		$TCCD_{50}$/0.1mL	1.50	1.50	
		$TCID_{50}$/0.1mL	≤1.50	≤1.50	
		Log_{10} Reduction	≥3.75	≥3.75	
498091-06 **4.5 minutes**	Influenza A (H3N2), Strain A/Victoria/361/2011 (ATCC/IRR FR-1061)	10^{-1} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	4.50
		$TCID_{50}$/0.1mL	≤0.50	≤0.50	
		Log_{10} Reduction	≥4.00	≥4.00	
498091-07 **9 minutes**	Human Rotavirus (Group A), Strain Wa (TC-Adapted) (ATCC VR-2018)	10^{-1} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	4.50
		$TCCD_{50}$/0.1mL	1.50	1.50	
		$TCID_{50}$/0.1mL	≤1.50	≤1.50	
		Log_{10} Reduction	≥3.00	≥3.00	
			Lots 2CB064A/BT3 2218	**Lots 2CB064B/BT3 0898**	
498091-08 **10 minutes**	Porcine Epidemic Diarrhea Virus, Strain Colorado 2013 Isolate	10^{-3} to 10^{-6}	Complete	Complete	5.50
		TCD_{50}/0.2mL	2.50	1.50	
		$TCID_{50}$/0.2mL	≤2.50	≤2.50	
		Log_{10} Reduction	≥3.00	≥3.00	

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, Sterilex Ultra Disinfectant Cleaner Solution 1 (1part) combined with Sterilex Ultra Activator Solution (1 part) and diluted in 400 ppm hard water (10 parts), as a disinfectant with bactericidal activity against the following microorganism, on hard, nonporous surfaces for a 9 minute contact time in the presence of 5% organic soil load:

MRID 498091-01 *Salmonella enterica* (ATCC 13076)
MRID 498091-02 *Salmonella enterica* (ATCC 8326).
MRID 498091-03 *Trichophyton mentagrophytes* (ATCC 9533)
MRID 498091-04 *Campylobacter jejuni* (ATCC 29428)

2. The submitted efficacy data support the use of the product, Sterilex Ultra Disinfectant Cleaner Solution 1 (1 part) combined with Sterilex Ultra Activator Solution (1 part) and diluted in 400 ppm hard water (10 parts), as a **disinfectant with virucidal activity** against the following microorganisms, on hard, nonporous surfaces for a 5 minute contact time in the presence of 5% organic soil load:

MRID 498091-05 Feline Calicivirus, Strain F-9 (ATCC VR-782) 9 minutes 5% organic soil
MRID 498091-07 Human Rotavirus (Group A), Strain Wa (TC-Adapted) (ATCC VR-2018) 9 minutes 5% organic soil

MRID 498091-08	Porcine Epidemic Diarrhea Virus, Strain Colorado 2013 Isolate no organic soil	10minutes
MRID 498091-06	Influenza A (H3N2), Strain A/Victoria/361/2011 (ATCC/IRR FR-1061) 5% organic soil dilution (1:1:64)	4.5 minutes

3. The submitted efficacy data (MRID 498091-03) support use of the product, Sterilex Ultra Disinfectant Cleaner Solution 1 (1part) combined with Sterilex Ultra Activator Solution (1 part) and diluted in 400 ppm hard water (10 parts), as a **disinfectant with fungicidal activity** against *Trichophyton mentagrophytes* (ATCC 9533), on hard, nonporous surfaces for a 9 minutes contact time in the presence of 5% organic soil load.

VII. LABEL

1. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Activator Solution (one part) and diluted in 8-10 parts of water, is an effective disinfectant against the following bacteria, when used for a contact time of 10 minutes, in the presence of 5% organic soil load, and at room temperature (20°C); **are supported** by the applicant's data.

Salmonella enterica (ATCC 13076)
Salmonella enterica (ATCC 8326).
Campylobacter jejuni (ATCC 29428)

2. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Activator Solution (one part) and diluted in 8-10 parts of water, is an effective disinfectant against the following viruses, when used for a contact time of 10 minutes, in the presence of 5% organic soil load, and at room temperature (20°C); **are supported** by the applicant's data.

Feline Calicivirus, Strain F-9 (ATCC VR-782)
Human Rotavirus (Group A), Strain Wa (TC-Adapted) (ATCC VR-2018)

3. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Activator Solution (one part) and diluted in 64 parts of water, is an effective disinfectant against Influenza A (H3N2), Strain A/Victoria/361/2011 (ATCC/IRR FR-1061), when used for a contact time of 5 minutes, in the presence of 5% organic soil load, and at room temperature (20°C); **are supported** by the applicant's data

4. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Activator Solution (one part) and diluted in 8-10 parts of water, is an effective disinfectant against the spoilage organism *Trichophyton mentagrophytes* (ATCC 9533), when used for a contact time of 10 minutes, in the presence of 5% organic soil load, and at room temperature (20°C); **are supported** by the applicant's data

5. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Activator Solution (one part) and diluted in 8-10 parts of water, is an effective disinfectant against Porcine Epidemic Diarrhea Virus, Strain Colorado 2013 Isolate, when used for a contact time of 10 minutes, **in the presence of 5% organic soil load (one step)**, and at room temperature (20°C); **are not supported** by the applicant's data. Virus was tested without soil load. Registrant must include pre-clean of surfaces before disinfection treatment for this claim to be acceptable.

6. **The applicant must make the following changes to the proposed label:**

- Revise all cross-contamination claims/references to read "cross-contamination on treated surfaces."
- On page 1, qualify the term "virucide" to the viruses tested.
- On pages 1 and 3, revise the statement "For disinfectant and public health use sites..." to read "For disinfection and non-food contact surface sanitization uses..."
- On pages 1, 3 and 20 revise the statement "For biocide and non-public health use sites..." to read "For uses other than disinfection and sanitization..."
- On page 1, revise "Sanitizer" to read "Non-food contact surface sanitizer."
- Moving the "directions for use" heading from page 3 to page 6 (before the pre-cleaning instructions) is recommended.
- On page 7, add a step to remove gross filth under the sanitizing directions.
- On page 9, revise use claims for Porcine Epidemic Diarrhea (PDE) Virus, Strain Colorado 2013 Isolate to include surface pre-cleaning before application for disinfection.
- On page 11, remove the statement "and sanitization" from the disinfection section at the bottom of the page since this section includes specific uses for food-contact surfaces.
- On page 12, revise the statement "and sanitization" in the disinfection section at the bottom of the page to read "and sanitization of non-food contact surfaces."
- On page 20, revise the term "bactericide" to read "bactericide against non-public health organisms."